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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,211

02/13/2004

Markku Anttila

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,211	Applicant(s) ANTTILA, MARKKU	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments

1. The amendment filed on 2/25/09 has been entered.
2. The response filed on 2/25/09 has been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-5 and 7-13 are pending.
5. The rejection of claims 1 and 3-5 under 35 U.S.C. 102(b) as being anticipated by Anttila Head & Neck Cancer, (1997) as evidence by Kangas (1990) is withdrawn because Applicant argues that toremifene administered by Anttila has a different structure from ospemifene.
6. Claims 1-5 and 7-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Anttila (1997) in view of Blom et al. (US 6984665) as evidence by Kangas, (1990) for the reasons made of record in Paper No. 20090225 and as follows.

Applicant argues that Anttila's reference is misinterpreted by believing that Anttila teaches administration of a metabolite of toremifene. Applicant also argues that Anttila teaches away from the claimed invention stating Anttila discloses that "toremifene "can

be taken equally well in fasted conditions or with meals." The t_{max} (time to peak concentration) was delayed from 2.3 hours to 4.0 hours, but the C_{max} (peak concentration), AUC (area under the curve), and $t_{1/2}$ values "were not significantly different" following a 14 hour fast compared to a standard high fat meal". Applicant also argues that toremifene is not ospemifene and the assumption by the Examiner that the data are unpersuasive is based on an erroneous premise.

Applicant also argues unexpected results that "the present application discloses that the effect of food intake on ospemifene absorption is 2-3 fold higher than in the fasted state (page 4, lines 4-5), that the effect of food also increases the bioavailability of ospemifene in the fed state as compared to the fasted state. (see e.g., Figures 1 and 2), that the Examiner attempts to discredit the evidence of unexpected superior results by arguing that Anttila teaches the administration of an "identical" chemical composition and that one would expect "identical" compositions to have the same properties".

In Response although Anttila did not administer the same drug, it is known in the art that toremifene metabolizes to give the same metabolites claimed in vivo as taught by Kangas. Administration of a drug that metabolizes to the active form in vivo is the same as administering the metabolite (i.e., TORE VI), see Kangas, page 9, Fig. I) and as claimed.

The effect of food intake on ospemifene absorption as 2-3 fold higher than in the fasted state (page 4, lines 4-5) is considered but is not persuasive because claim 1 merely recites inherent properties of the compound when "taken shortly before" (i.e., in a fasting mode) or "during or after administering the compound". The unexpected

result stated on page 4, lines 4-5 is only that "while food intake causes only a 20% increase of raloxifene absorption, the effect on ospemifene absorption is a 2-3 fold increase". In contrast the claims encompass three variables (i.e., shortly before, during and after).

Therefore, contrary to Applicant's assertion, the argument only concentrates on the single reference Anttila and fails to state why the combination of Anttila and Blom would not have been obvious to one of ordinary skill in the art.

Careful consideration has been given to Applicant's arguments but they are not persuasive for the reasons given above.

7. Claims 1 and 8-9 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent Application No. 11201098 for the reasons made of record in Paper No. 20090225 and as follows.

This rejection is maintained for the same reasons that the 103 rejection is maintained above. In this instance Applicant's alleging that Anttila teaches away from the claimed invention is not persuasive. As previously evidenced by Melander et al, it would have been obvious to one of ordinary skill in the art to check the bioavailability of food effect on drugs before administration.

Applicant also argues that the "disclosure is to enhancing bioavailability will not change treating atrophy because as soon as the dug is available treating will proceed".

In response even though Applicant asserts that the instant claims are directed to “enhancing bioavailability.....”, dependent claims 8 also recites treating skin atrophy with the same compound. Whether or not the instant claims are directed to bioavailability there is no distinguishing step that indicates once the drug is administered it would not treat skin atrophy. Applicant’s argument that the disclosure is to enhancing bioavailability will not change treating atrophy, because as soon as the drug is available, treating will proceed.

Careful consideration has been given to Applicant's arguments but they are not persuasive for the reasons’ given above and the same argument is applied to the rejection below.

8. Claims 1-9 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6984665 for the reasons made of record in paper No. 20090225 and as follows.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. V. G./
Examiner, Art Unit 1618
5/5/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649